

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)	Application Number		10521040
	Filing Date		2005-08-16
	First Named Inventor	Herman Jan Tijmen Coelingh Bennink et al.	
	Art Unit	1616	
	Examiner Name	Mei-Ping Chui	
Attorney Docket Number		0470-050079	

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	6	5340586		1994-08-23	Pike et al.		
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9	5063507	1991-11-05	Lindsey et al.	
10	4762717	1988-08-09	Crowley, Jr.	
11	4722941	1988-02-02	Eckert et al.	
12	4624665	1986-11-25	Nuwayser	
13	4573996	1986-03-04	Kwiatek et al.	
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	6	19917930	DE	A1	2000-10-19	Schering		<input type="checkbox"/>
	7	9858657	WO	A1	1998-12-30	Mannaerts et al		<input type="checkbox"/>
	8	9603929	WO	A1	1996-02-15	Biex, Inc.		<input type="checkbox"/>
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	10	9502408	WO	A1	1995-01-26	Schering		<input type="checkbox"/>
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2	VISSER et al., "First human exposure to exogenous single-dose oral estetrol in early postmenopausal women," CLIMACTERIC (2008) 11(1): 1-10.	<input type="checkbox"/>
3	VISSER et al., "Clinical applications of estetrol," J. Of Steroid Biochem and Molecular Biol. (2009) 114: 85-89.	<input type="checkbox"/>
4	HOLINKA et al., "Estetrol: A unique steroid in human pregnancy," J. of Steroid Biochem and Molecular Biol. (2009) 110: 138-143.	<input type="checkbox"/>
5	COELINGH BENNINK et al., "Oral bioavailability and bone sparing effects of estetrol in an osteoporosis model," CLIMACTERIC (2008) 11 (Supp 3): 1-13.	<input type="checkbox"/>
6	ALBERTAZZI PAOLA et al., "The Effect of Tibolone Versus Continuous Combined Norethisterone Acetate and Oestradiol on Memory, Libido and Mood of Postmenopausal Women: A Pilot study"; Database Biosis 'Online'; 10/31/2000; pages 223-229; Vol. 36, No. 3; Biosciences Information Service, Philadelphia, PA., U.S.	<input type="checkbox"/>
7	ALLEN ET AL., An Ovarian Hormone: Preliminary Report on Its Localization, Extraction and Partial Purification, and Action in Test Animals, JAMA, September 8, 1923, Vol. 81, pp. 819-821.	<input type="checkbox"/>
8	ALLEN ET AL., The Induction of a Sexually Mature Condition in Immature Females by Injection of the Ovarian Follicular Hormone, Am. J. Physiol., 1924, Vol. 69, pp. 577-588.	<input type="checkbox"/>
9	JONES ET AL., The Effects of Various Steroids on the Vaginal Histology in the Rat, Fertility and Sterility, April 1973, Vol. 24, No. 4, pp. 284-291.	<input type="checkbox"/>
10	TULCHINSKY ET AL., Plasma Esterol as an Index of Fetal Well-Being, J. Clin. Endocrinol. Metab., 1975, Vol 40. Pp. 560-567.	<input type="checkbox"/>
11	HAMMOND ET AL., A Versatile Method for the Determination of Serum Cortisol Binding Globulin and Sex Hormone Binding Globulin Binding Capacities, 1983, Vol. 132, pp. 101-110.	<input type="checkbox"/>
12	ELGER ET AL., Sulfamates of Various Estrogens are Prodrugs with Increased Systemic and Reduced Hepatic Estrogenicity at Oral Application, J. Steroid Biochem. Molec. Biol., 1995, Vol. 55, No. 3 / 4, pp. 395-403.	<input type="checkbox"/>

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13	MURPHY ET AL., Endometrial Effects of Long-Term Low-Dose Administration of RU486, Fertility and Sterility, April 1995, Vol. 63, No. 4, pp. 761-766.	<input type="checkbox"/>
14	REEL ET AL., Survey and Assessment of Mammalian Estrogen Biological Assays for Hazard Characterization, Fundamental and Applied Toxicology, 1996, Vol. 34, pp. 288-305.	<input type="checkbox"/>
15	BERAL ET AL., Use of HRT and the Subsequent Risk of Cancer, Journal of Epidemiology and Biostatistics, 1999, Vol. 4, No. 3, pp. 191-215.	<input type="checkbox"/>
16	TAVANI ET AL., The Adverse Effects of Hormone Replacement Therapy, Drugs & Aging, May 1999, Vol. 14, No. 5, pp. 347-357.	<input type="checkbox"/>
17	PIKE ET AL., Progestins and Menopause: Epidemiological Studies of Risks of Endometrial and Breast Cancer, Steroids, 2000, Vol. 65, pp. 359-664.	<input type="checkbox"/>
18	AVVAKUMOV ET AL., Steroid-binding Specificity of Human Sex Hormon-binding Globulin Is Influenced by Occupancy of a Zinc-binding Site, The Journal of Biological Chemistry, August 25, 2000, Vol. 275, No. 34, pp. 25920-25925.	<input type="checkbox"/>
19	HOLINKA, ET AL., "Comparison of Effects of Esterol and Tamoxifen with Those of Estriol and Estradiol on the Immature Rat Uterus", Biology of Reproduction, Society for the Reproduction Society for the Study of Reproduction, Champaign, IL, US, 1980, Vol. 22, No. 4, pp. 913-926.	<input type="checkbox"/>
20	JANSSON ET AL., "Estrogen Induces a Potent Suppression of Experimental Autoimmune Encephalomyelitis and Collagen-Induced Arthritis in Mice", Journal of Neuroimmunology, Elsevier Science Publishers BV XX, 1994, Vol. 53, No. 2, pp. 203-207.	<input type="checkbox"/>
21	ERDBRUEGGER ET AL., Drug Discovery Today: Disease Mechanisms (2004), Vol. 1, pp. 73-81.	<input type="checkbox"/>
22	Lab Tests Online (www.labtestsonline.org/understanding/conditions/autoimmune.html) retrieved on 10/15/2009.	<input type="checkbox"/>
23	www.tiscali.co.uk/lifestyle/e/healthfitness/health_advice/netdoctor/archive/000489.html , 10/15/2009.	<input type="checkbox"/>


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24	MedlinePlus Medical Encyclopedia: Multiple Sclerosis, retrieved on 03/28/2008 via www.nlm.nih.gov/medlineplus/ency/article/000737.htm, dated on 08/06/2007, Page 1 and 2; also see WebMD: Multiple Sclerosis - Prevention, retrieved on 03/28/2008 via www.webmd.com/multiple-sclerosis/multiple-sclerosis-ms-prevention, dated on 03/23/2006.	<input type="checkbox"/>
25	MedlinePlus Medical Encyclopedia: rheumatoid arthritis, retrieved on 03/28/2008 via www.nlm.nih.gov/medlineplus/ency/article/000431.htm, dated on 07/27/2007, page 1-2 and 4; also WebMD: Rheumatoid Arthritis - Prevention, retrieved on 03/28/2008 via www.webmd.com/rheumatoid-arthritis/rheumatoid-arthritis-prevention, dated on 08/23/2006.	<input type="checkbox"/>
26	MUECK et al., "Angio and Anti-Angiogenic Effects of Estradiol and its Metabolites", J. Clin. Basic Cardiol., 2001, pp. 153-155, Vol. 4, No. 2.	<input type="checkbox"/>
27	SHAH et al., "Estrogen and Skin. An Overview", Am. J. Clin. Dermatol., 2001, pp. 143-150, Vol. 2, No. 3.	<input type="checkbox"/>
28	SITRUK-WARE et al., "Local Hormonal Treatment for Urogenital Atrophy After Menopause", Schweiz. Rundsch. Med. Praxis, 1997, pp. 1245-1248, Vol. 86, No. 33, and SITRUK-WARE, English Translation, 1997. Praxis, Schweizerische Rundschau für Medizin, Vol. 86, No. 33, pp 1-13	<input type="checkbox"/>
29	SCHMIDT et al., "Treatment of Skin Aging with Topical Estrogens", Int. J. Dermatol., 1996, pp. 669-674, Vol. 35, No. 9.	<input type="checkbox"/>
30	YOUNGLAI ET AL., Journal of Clinical Endocrinology and Metabolism, 1968, Vol. 28, Issue 11, pp 1611-1617.	<input type="checkbox"/>
31	Webster Ninth New Collegiate Dictionary, 2000, Definition of Prevention, pg 1.	<input type="checkbox"/>
32	WILLHITE ET AL., Pharmacotherapy, 2001, Vol. 21, Issue 4, pp 464-480.	<input type="checkbox"/>
33	SEEGER et al., "The inhibitory effect of endogenous estrogen metabolites on copper-mediated in vitro oxidation of LDL", Int. Journal of Clinical Pharmacology and Therapeutics, (1998), Vol. 36, No. 7, pp 383-385.	<input type="checkbox"/>
34	KUIPERS ET AL., "Enterohepatic Circulation in the Rat", Gastroenterol., Vol. 88, pp 403-411 (1985).	<input type="checkbox"/>

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	35	SCHWARTZ, "A Model for the Regulation of Ovulation in the Rat", Recent Prog. Horm. Res., Vol. 25, pp 1-55, (1969).	<input type="checkbox"/>
	36	BEATTIE ET AL., "The Differential Effects of Diestrous Progestogen Administration on Proestrous Gonadotrophin Levels, Endocrinol", Vol 97, pp. 885-890, (1975).	<input type="checkbox"/>
	37	DE VISSER ET AL., "Endocrinological Studies with (7a, 17 a)-17-Hydroxy-7-me norpregn-5(10)-en-20-yn-3-one (Org OD 14), Arzneim, Forsh., Vol. 34, pp 1010-1020, (1984).	<input type="checkbox"/>

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